

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	MDL No. 1456
AVERAGE WHOLESALE PRICE LITIGATION)	Master File No. 01-12257-PBS
)	Subcategory Case No. 06-11337
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti B. Saris
)	
<i>State of California ex rel. Ven-A-Care of the Florida</i>)	
<i>Keys, Inc. v. Abbott Labs, Inc. et al.,</i>)	
Civil Action No. 03-11226-PBS)	
)	

**STATEMENT OF UNDISPUTED MATERIAL FACTS IN
SUPPORT OF MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S
MOTION FOR PARTIAL SUMMARY JUDGMENT**

Pursuant to Local Rule 56.1, Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") submit this statement of the material facts of record as to which there is no genuine issue to be tried in support of its Motion for Partial Summary Judgment. Mylan also refers the Court to Defendants' Joint Statement of Undisputed Material Facts (the "Joint Statement") and Joint Motion for Partial Summary Judgment.

A. Several States and the Federal Trade Commission Sued Mylan for Increasing the Price of Lorazepam and Clorazepate

1. On December 21, 1998, thirty-three states filed a joint complaint in the United States District Court for the District of Columbia against Mylan Inc., Cambrex Corporation, Profarmaco S.r.l., Gyna Laboratories of America, Inc. and SST Corporation in the action entitled *State of Connecticut, et. al. v. Mylan Laboratories Inc., et al.*, Civ. No. 1:98-CV-3115-TFH (D.D.C.).¹ (See Palermo Decl., Ex. A, at CAMylan 04005432-3.)

¹ The states' joint complaint was amended on February 8, 1999, May 13, 1999 and February 1, 2001. (Palermo Decl., Ex. A, at ¶ II(T).)

2. On the same day, the Federal Trade Commission (“FTC”) filed a separate complaint (the “FTC Complaint”) in the United States District Court for the District of Columbia against Mylan Inc. and the Lorazepam/Clorazepate Defendants pursuant to Section 13(b) of the Federal Trade Commission Act in the action entitled *FTC v. Mylan Laboratories Inc., et al.*, Civ. No. 1:98-CV-3114-TFH (D.D.C.) (See Palermo Decl., Ex. B).

3. The actions brought by the FTC and the thirty-three states were later consolidated into one proceeding entitled *In re Lorazepam & Clorazepate Antitrust Litig.*, MDL No. 1290 (TFH), Misc. No. 99ms276 (TFH) (D.D.C.) (the “Lorazepam/Clorazepate Action”). (Palermo Decl., Ex. A).

4. The states’ joint complaint, as amended on February 1, 2001 (the “Joint Third Amended Complaint”), alleged that the states acted “by and through their Attorneys General...on behalf of their respective States’ general economies in their sovereign capacities; and/or in their proprietary capacities on behalf of department bureaus and agencies of state government...as *reimbursers under state Medicaid* and other programs.” (Palermo Decl., Ex. C, at ¶7 (emphasis added).)

5. California joined in and adopted each of the allegations in the Joint Third Amended Complaint. (Palermo Decl., Ex. C, at ¶¶ 104-105.) Moreover, California specifically alleged that the Mylan’s practices were in violation of California’s consumer protection statute and California’s antitrust statute. (Palermo Decl., Ex. C, at ¶¶ 104-105.)

6. The Joint Third Amended Complaint further alleged that “[i]n 1997, Mylan [Inc.] embarked on a strategy to raise the prices of some of its generic drugs and maintain these prices at inflated levels, thereby increasing the profitability of these drugs.” (Palermo

Decl., Ex. E, at ¶ 35.) The FTC Complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 19.)

7. The Joint Third Amended Complaint further alleged that “[t]he acts and practices of the Defendants...have had the purpose or effect...to restrain competition unreasonably and to injure competition....” (Palermo Decl., Ex. C, at ¶ 51.) The FTC Complaint alleged similar allegations. (Palermo Decl., Ex. B, at ¶ 34.)

8. The Joint Third Amended Complaint further alleged that “*one* part of [Mylan Inc.’s] [alleged] strategy” involved improper agreements for the supply of active pharmaceutical ingredients. (Palermo Decl., Ex. C, at ¶ 35.) The FTC Complaint states similar allegations. (Palermo Decl., Ex. B, at ¶¶ 32, 33.)

9. The Joint Third Amended Complaint further alleged that on “January 12, 1998 despite no significant increase in its costs, Mylan [Inc.] raised its price of Clorazepate tablets...by amounts ranging from 1,900 percent to over 3,200 percent, depending on the bottle size and strength. *For example, a 500-count bottle of 7.5 mg Clorazepate tablets increased in price from \$11.36 to \$377.00. The ultimate retail price to consumers was even higher*” and on “March 3, 1998, despite no significant increase in its costs, Mylan [Inc.] raised its price of Lorazepam tablets by amounts ranging from 1,900 percent to over 2,600 percent, depending on the bottle size and strength. *For example, a 500-count bottle of 1mg Lorazepam tablets increased in price from \$7.30 to \$191.50. The ultimate retail price to consumers was even higher.*” (Palermo Decl., Ex. C, at ¶ 45 (emphasis added).) The FTC complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 28.)

10. The Joint Third Amended Complaint further alleged that “[o]n January 12, 1998...Mylan raised its price of clorazepate tablets to State Medicaid programs”, that “[o]n

March 3, 1998...Mylan raised its price of Lorazepam tablets”, and that “[a]fter the above-mentioned price increases were effected, departments, bureaus, or agencies of the governments of some States (or such States’ assignors) purchased Lorazepam or Clorazepate tablets at supra-competitive prices from Mylan [Inc.] or its subsidiaries....” (Palermo Decl., Ex. C, at ¶ 45.) The FTC Complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 29.)

11. The Joint Third Amended Complaint alleged increases in market share and profits to Mylan Inc. derived from sales to many different types of customers, including “pharmacies, hospitals, insurers, managed care organizations, wholesalers, government agencies, patients, consumers, and others....” (Palermo Decl., Ex. C, at ¶ 47.)

12. The Joint Third Amended Complaint further alleged that the effect of the increase in the AWP and WAC prices of Mylan’s Lorazepam/Clorazepate raised “the cost that...*government agencies*...pay for Lorazepam and Clorazepate tablets.” (Palermo Decl., Ex. C, at ¶ 54, *see also* ¶¶ 104, 105 (emphasis added).)

13. The Joint Third Amended Complaint further alleged that “[a]s a result of these substantial and unprecedented agreements and price increases for Lorazepam and Clorazepate tablets, many purchasers, including...*government agencies*...have paid substantially higher prices.” (Palermo Decl., Ex. C, at ¶ 47.) The FTC Complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 31.)

14. The Joint Third Amended Complaint further alleged that the anticompetitive effects alleged against Mylan Inc. included: “[r]aising the cost that...*government agencies*...pay for Lorazepam and Clorazepate tablets.” (Palermo Decl., Ex. C, at ¶ 54.) The FTC complaint stated the same allegations. (Palermo Decl., Ex. B, at ¶ 47.)

15. The Joint Third Amended Complaint further alleged that “[a]s a direct and proximate result of the unlawful conduct alleged above, the States were not and are not able to...pay reimbursements for purchases of Lorazepam and Clorazepate at prices determined by free and open competition...and have paid more and continue to pay more...than they would have paid in a free and open competitive market” and that Mylan Inc. “unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits.” (Palermo Decl., Ex. C, at ¶ 57-60 (emphasis added).) The FTC Complaint alleged similar allegations. (Palermo Decl., Ex. B, at ¶ 30-31, 34.)

B. Mylan and California Agree to Settle the Lorazepam/Clorazepate Action

16. On January 30, 2001, after “extensive analysis of the pertinent facts” and “extensive arms-length negotiation,” Mylan Inc., the FTC and the various states entered into an agreement entitled the “Settlement Agreement Between Plaintiff States, The Federal Trade Commission And Mylan Laboratories, Inc., GYMA Laboratories Of America, Inc., Profarmaco S.R.L., Cambrex Corp.” (the “Lorazepam/Clorazepate Settlement”). (Palermo Decl., Ex. D, at CaMylan04005202- 5203.)

17. California was a party to the Lorazepam/Clorazepate Settlement. (Palermo Decl., Ex. D, at Section I(N) at CAMylan 04005207.)

18. In Section IV(A) of the Lorazepam/Clorazepate Settlement, Mylan Inc. agreed to pay \$100 million in full and final settlement of the claims asserted against Mylan Inc. in exchange for the release of all Released Claims, as defined in Section I(U) of the Lorazepam/Clorazepate Settlement. (Palermo Decl., Ex. D, at Section IV(A) at CAMylan 04005211.)

19. In the Lorazepam/Clorazepate Settlement, California agreed to “release[] and “forever discharge[]” Mylan Inc. and all of its subsidiaries and affiliates from:

[A]ll claims, counterclaims, set-offs, demands, actions, rights, liabilities, and causes of action arising under federal or state antitrust, unfair methods of competition, or consumer protection laws, under state or federal unfair or deceptive trade practices acts, or under common law, asserted or that could have been asserted...by the Plaintiff States on behalf of state agencies...arising from the facts, matters, transactions, events, occurrences, acts, disclosures, statements, omissions, or failures to act set forth or alleged in the [Joint Third Amended Complaint]....

(Palermo Decl., Ex. D, at Sections I(U), I(Y), and IV(D).)

20. In the Lorazepam/Clorazepate Settlement, California agreed to the dismissal with prejudice of its claims in the Joint Third Amended Complaint. (Palermo Decl., Ex. D, at Section VII(C) and Attachment 2.)

21. Nothing in the terms of the Lorazepam/Clorazepate Settlement required Mylan to change the prices for its Lorazepam/Clorazepate products or to change its pricing practices. (*See generally* Palermo Decl., Ex. D.)

22. The terms of the Lorazepam/Clorazepate Settlement state that the settlement is governed by New York law. (Palermo Decl., Ex. D, at Section XI(H).)

23. On February 1, 2001, the Lorazepam/Clorazepate Settlement was filed with the District Court for the District of Columbia. (*See generally* Palermo Decl., Ex. A.)

24. On February 1, 2001, California joined in a request with the other states for approval of the Lorazepam/Clorazepate Settlement. (*See* Palermo Decl., Ex. A, at Sections II(U), (T).)

25. On April 27, 2001, the District Court of the District of Columbia preliminarily approved the Lorazepam/Clorazepate Settlement. (Palermo Decl., Ex. E.)

26. The Lorazepam/Clorazepate Settlement including the release contained therein “shall be governed by, and construed in accordance with the laws of the State of New York without regard to its conflict of laws principles.” (Palermo Decl., Ex. D, at Section XI(H).)

C. The Lorazepam/Clorazepate Settlement is Finally Approved and Judgment is Rendered in the Lorazepam/Clorazepate Litigation

27. On February 1, 2002, the District Court for the District of Columbia entered an order and final judgment granting final approval of the Lorazepam/Clorazepate Settlement (the “Order and Final Judgment”). (Palermo Decl., Ex. A.)

28. The Order and Final Judgment dismissed the various states’ prior complaints “with prejudice” and applied to Mylan Inc. and its affiliates (Palermo Decl., Ex. A, at Sections II(AA) and VI(A).)

29. The Order and Final Judgment states that Mylan Inc. and the various states, including California, “executed a settlement agreement” in order to “resolve any and all disputes arising from the [prior complaints].” (Palermo Decl., Ex. A, at CaMylan04005428-CaMylan04005429.)

30. The Order and Final Judgment barred California, as one of the states parties to the Lorazepam/Clorazepate Settlement, “from further prosecution of the Released Claims” and further stated that Mylan Inc. and its subsidiaries and affiliates “are released and forever discharged from liability for the Released Claims.” (Palermo Decl., Ex. A, at Section VI(A).)

31. The Order and Final Judgment dismissing the Lorazepam/Clorazepate Action “adjudicate[d] all the claims, rights and liabilities of the parties, and is final and shall be immediately appealable.” (Palermo Decl., Ex. A, at Section VIII.)

32. The Order and Final Judgment states that the “terms of the Settlement Agreements are adjudged as fair, reasonable and adequate and in the best interests of consumers in the Plaintiff States and the Settlement Group as a whole, and satisfy the requirements of Federal Rule of Civil Procedure 23(e), state *parens patriae* laws and/or state equitable authority and due process.” (Palermo Decl., Ex. A, at Section IV(C).)

D. Mylan Completed Its Obligations Under the Lorazepam/Clorazepate Settlement

33. Mylan paid, through an escrow agent, “\$100 million in full and final settlement” of the Lorazepam/Clorazepate Action. This amount was divided into the Agency Account of the State Fund and the Consumer Fund. The funds from these accounts were distributed to the states. (See Palermo Decl., Ex. D, at Sections IV, V, and VI.)

34. On or about August 25, 2005, approximately three years after the final approval of the Lorazepam/Clorazepate Settlement and Mylan Inc.’s completion of its obligations under the Lorazepam/Clorazepate Settlement, California intervened in the present action. (Palermo Decl., Ex. F.)

E. Mylan Inc. Is Not A Proper Party To This Action

35. California alleges that Mylan Inc. manufactured, marketed, and sold the Mylan generics during the relevant time period. (Palermo Decl., Ex. F, at ¶¶ 16, 123-128.)

36. Mylan Inc. is a holding company and did not manufacture, market, or sell the Mylan generics. (Palermo Decl.; Ex. H, at 70:18-71:5; Ex. G, at Response to Interrogatory No. 6.)

37. Mylan Pharmaceuticals Inc., not Mylan Inc., manufactured and sold the Mylan generics during the relevant time period. (Palermo Decl., Ex. I, at 44:2-45:10.)

38. Mylan Pharmaceuticals Inc. reported the AWP prices for the Mylan generics during the relevant time period. (Palermo Decl., Exs. J, K, L, M, N.)

Dated: November 25, 2009

Respectfully submitted,

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/s/ Christopher C. Palermo

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on November 25, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Christopher C. Palermo
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